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IN THE

Supreme Court of the United States

MYLAN LABORATORIES, INC., MYLAN PHARMACEUTICALS, INC., & UDL LABORATORIES, INC.,

Petitioners,

v.

TAKEDA CHEMICAL INDUSTRIES, LTD. & TAKEDA PHARMACEUTICALS NORTH AMERICA, INC.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

REPLY BRIEF FOR PETITIONERS

WILLIAM A. RAKOCZY
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 W. Hubbard St.
Chicago, IL 60654

THOMAS C. GOLDSTEIN
Counsel of Record
CHRISTOPHER M. EGLESON
JONATHAN H. EISENMAN
AKIN GUMP STRAUSS HAUER & FELD LLP
1333 New Hampshire Ave., NW
Washington, DC 20036
(202) 887-4000

Attorneys for Petitioners

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

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REPLY BRIEF FOR PETITIONERS

STATEMENT

1. Respondents contend that the rulings below rest on no contestable proposition of law, but instead reflect the application of settled principles to supposedly extreme facts. That assertion misstates the history and record of this case.

In filing their ANDA and providing respondents with the statutory notice letter, petitioners stated their view that respondents' patent was invalid. The statute then worked as Congress intended: having engaged in a nominal, "artificial" act of patent infringement, petitioners were sued by respondents.

After the parties conducted appropriate discovery, providing petitioners with additional information about respondents' patent (as the discovery rules are designed to do), petitioners identified new evidence that the patent was invalid as obvious. The district court disallowed petitioners' request to proceed to trial on that theory of obviousness, however, and later cited petitioners' post-discovery change in theory as misconduct that supported awarding attorney fees to respondents. Specifically, the district court faulted petitioners for failing to state a prima facie case of invalidity in their pre-suit notice letter. Pet. App. 66a. The district court also held that Mylan subsequently "engaged in further misconduct, attempting to substitute a new theory of obviousness following the close of fact discovery." Pet. App. 95a.

Petitioners appealed to the Federal Circuit, explaining that the district court committed legal error in faulting petitioners for changing theories after discovery. The court of appeals held that "it seems reasonable to expect assertions of invalidity based on prior art to remain relatively consistent," and approved awarding attorney fees based *inter alia* on an ANDA applicant's change in arguments. *See* Pet. App. 10a. As the language respondents themselves excerpt demonstrates, the court of appeals made clear that it would review the district court's assessment of petitioners' "entire strategy" as a whole, and only for "clear error." BIO 20 (quoting Pet. App. 16a). The court of appeals also affirmed the district court's reliance on its earlier decision in *Yamanouchi Pharmaceutical Co., Ltd. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1347 (Fed. Cir. 2000), in which the court of appeals had articulated the prima facie standard that

the district court applied in reviewing petitioners' ANDA notice letter.

2. The petition explained that the prima facie standard that the district court applied in assessing whether petitioners' ANDA was filed in good faith, which the court of appeals approved, was erroneous. The district court asked whether the statutory notice letter stated a prima facie claim of invalidity, a standard higher than that required to plead a cause of action for infringement and one that has no basis in law. Pet. 16; *see Swierkiewicz v. Sorema, N.A.*, 534 U.S. 506, 511 (2002) (complaint need not state prima facie case). Respondents' argument to the contrary confuses the *detail* required to be stated in a notice letter with the *standard of proof* to which the ANDA filing is held. The petition explained that the notice letter's only function is to "set the stage for litigation" and correctly noted that, once litigation begins, the contents of the notice letter are no longer legally relevant. Pet. 17; *see Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1349 (Fed. Cir. 2004) (principal purpose for deeming the ANDA filing to be an act of infringement is to provide a "jurisdictional basis" for the litigation).

As long as the ANDA applicant has complied with the filing requirements of the statute and presented colorable arguments, it has discharged Congress's purpose. As *amicus curiae* the Generic Pharmaceutical Association notes, the ANDA approval process is not designed to test the legality of an applicant's claims, but is instead solely intended to "speed innovations that make drugs more effective, safer, and more affordable" while allowing the FDA to "assur[e] the safety, efficacy, and security of those drugs."

Brief of Generic Pharmaceutical Association as *Amicus Curiae* in Support of Petitioner ("GPhA Br.") at 4. The only requirement specified in the statute is that the notice letter accurately state the "factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." 21 U.S.C. § 355(j)(B)(iv).

After extensive litigation and discovery, a trial court attempting to determine whether the original notice letter stated a prima facie case risks coloring its analysis with its view of the merits of the parties' litigating positions, so there is every danger in supplementing Congress's statutory requirements with the prima facie rule invented by the courts below. Increasing the burden on an applicant beyond what Congress has required will frustrate Congress's purpose of promoting access to generic drugs. The court of appeals' approval of that entrenched standard (*see Yamanouchi*, 231 F.3d at 1347 (applying prima facie standard)) thus warrants this Court's review because it is error and because, as the petition explained, erroneously requiring a prima facie showing of invalidity in an ANDA applicant's notice letter will have the disastrous effect of deterring meritorious ANDA filings.

Respondents do not defend the prima facie rule of the courts below and do not dispute that it was legal error to ask whether an ANDA applicant's notice letter states a prima facie case of invalidity. Instead, respondents merely insist that they established bad faith "by clear and convincing evidence." BIO 22. But of course the quantum of proof in this or any case is meaningless if the proof is offered to answer the wrong question. The courts below were wrongly ask-

ing whether petitioners had stated a prima facie case of invalidity in order to ascertain whether their ANDA filing was in bad faith. It is no answer to the courts' error to say that a failure to state a prima facie case was proven overwhelmingly.

3. The district court's statement that a post-discovery change in theories was "misconduct" shows that that change contributed to the court's determination that this case was exceptional and merited an attorney fee award. Petitioners explained that allowing a change in theories to contribute to an attorney fee award, especially one as large as the more than $11 *million* award in this case, would chill meritorious Hatch-Waxman litigation and thus deter the introduction of valuable generic drugs.

Respondents' answer is to suggest that the change of theories was not in fact the basis for the Federal Circuit's ruling. In support, respondents note that the court of appeals stated that, in its view, the district court did not base its decision on the "mere fact that Mylan changed its theory of invalidity and then lost." BIO 20 (quoting Pet. App. 16a). And just as the court of appeals did, respondents go on to note purported evidence of "litigation misconduct" unrelated to the change in obviousness theories and to defend that evidence as sufficient to justify an award of attorney fees. *See ibid.* (noting that district court enumerated a variety of categories of misconduct).

But the district court's conclusions about the scope of petitioners' purported bad faith (Pet. App. 57a) and respondents' contention in turn that petitioners' bad faith was "pervasive throughout the litigation" (BIO 22) are question-begging. The district court's view of the scope of petitioners' purported misconduct rested

in substantial part on its mistaken conclusion that failing to state a prima facie case constituted misconduct in the first place (Pet. App. 66a), and in further part on its view that a change in theories after discovery also constituted misconduct (Pet. App. 95a).

In any event, respondents' discussion of other grounds that might have supported the district court's ruling, and the court of appeals' discussion of whether the district court relied on the "mere fact" of the change in theories standing alone, simply miss the point. The petition challenges the legal propriety of allowing a change in theories after discovery to constitute a substantial ground for an award of attorney fees. The rule that petitioners seek prohibiting consideration of such a change in theories would apply and would invalidate the award here regardless of whether other factors might independently justify such an award. Should the Court grant certiorari and hold for petitioners, the award would of course be vacated. In short, if a ground for the award was improper, it is no defense to that impropriety that other grounds might have supported that award. And that is particularly true where allowing the error to remain entrenched in Federal Circuit law will have all the deterrent consequences and harmful effects on consumers warned of in the petition.

4. As to those deterrent effects, respondents offer no answer other than to excerpt the Federal Circuit's discussion of those arguments, but reliance on the court of appeals' own analysis of the consequences of its decision begs the question once again. The court of appeals necessarily did not consider either its own articulation of the prima facie test for ANDA filings or the district court's reliance on petitioners' change

of theories to be error, and so of course it did not conclude that those standards would improperly deter the introduction of generic drugs in contravention of Congress's intent.

But in fact both are error, and those errors will deter meritorious ANDA filings and the litigation of meritorious theories. *See* GPhA Br. 11. The threat of being sanctioned with attorney fees will be a significant concern to any potential ANDA filer. And it is a threat that cannot be resolved ahead of time, since the ANDA filing will always be the first step in the path toward resolving the filer's claims of invalidity, and the award of attorney fees will generally be the last step in the resulting litigation. And since most proposed generics will be tested in the ANDA process, the risk of liability will affect a large number of filings.

This Court's intervention is thus required to correct the Federal Circuit's errors, because the availability of generic drugs is a matter of extreme importance. If potential ANDA filers are discouraged from filing meritorious claims, and if ANDA filers are deterred from litigating the best available theories, the result will be that holders of invalid patents will continue to hold wrongful monopolies on important drugs. Patients who cannot afford to pay the resulting inflated prices will go without, which is the wrong that Congress intended to fight by passing the Hatch-Waxman Act. This Court's review is thus warranted to ensure that Congress's purpose is carried out.

CONCLUSION

For the foregoing reasons and those stated in the petition, the petition for a writ of certiorari should be granted.

Respectfully submitted,

WILLIAM A. RAKOCZY
RAKOCZY MOLINO
MAZZOCHI SIWIK LLP
6 W. Hubbard St.
Chicago, IL 60654

THOMAS C. GOLDSTEIN
Counsel of Record
CHRISTOPHER M. EGLESON
JONATHAN H. EISENMAN
AKIN GUMP STRAUSS
HAUER & FELD LLP
1333 New Hampshire Ave., NW
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